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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE APPLICATION NO. H60-113 US 5172 10/654,184 · 09/03/2003 Sven-Erik Carlson **EXAMINER** 08/04/2005 21706 7590 KREMER, MATTHEW J NOTARO AND MICHALOS 100 DUTCH HILL ROAD ART UNIT PAPER NUMBER SUITE 110 ORANGEBURG, NY 10962-2100 3736

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application N	0.	Applicant(s)	_
055 4-45 0		10/654,184	10/654,184 CARLSON ET AL.		
	Office Action Summary	Examiner		Art Unit	
		Matthew J. Kre		3736	
Period fo	The MAILING DATE of this communication a or Reply	ppears on the cov	er sheet with the c	correspondence add	iress
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠	Responsive to communication(s) filed on 20 May 2005.				
,	This action is FINAL . 2b) This action is non-final.				
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposit	ion of Claims				
5)□ 6)⊠ 7)□	Claim(s) 1,5-8 and 10-19 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. Claim(s) 1,5-8 and 10-19 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or election requirement.				
Applicat	ion Papers			•	
9) The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority (under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachmer	at(s) ce of References Cited (PTO-892)	ا ر⊿	Interview Summary	(PTO-413)	
2) Notice 3) Infor	ce of References Cited (PTO-692) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/0 er No(s)/Mail Date <u>2/18/2005</u> .	5) bos) 6) b	Paper No(s)/Mail D Notice of Informal F)-152)

DETAILED ACTION

Response to Amendment

1. The listing of claim received with the Response to the Restriction/Election Requirement filed on 5/20/2005 was non-compliant because claim 20 is listed as previously presented and listed as cancelled. From the Applicant's arguments, it is clear that claim 20 was cancelled and the Examiner treated claim 20 as cancelled but the Applicant should correct this oversight in future correspondence in this Application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5-8, 10-14, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,348,003 to Caro. Caro teaches a measuring sensor that includes a light source 123 with a plurality of LEDs (Fig. 4 of Caro); two light receivers 304 (Fig. 5 of Caro); and means to increase the optical signal to noise ratio by using modulator 202. (Fig. 4 of Caro). Caro teaches the use of beam shaping elements 137

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(Fig. 4 of Caro) and 117 (Fig. 1 of Caro). Caro teaches the use of means for locating the measuring sensor adjacent the tissue by using clip 101. (Fig. 1 of Caro).

In regard to claims 5-6 and 8, Caro teaches LEDs 136 (Fig. 4 of Caro), photodetecting elements 304 (Fig. 5 of Caro), and optical filters disposed between the light sources and the photodetecting elements (column 10, lines 41-56 of Caro). In regard to claim 7, the detectors are sensitive to the frequency of the light. (column 11 lines 28-32 of Caro). In regard to claim 10, Caro teaches a modulator 202. (Figs. 3-4 of Caro). In regard to claims 11-13, Caro teaches that the modulation can be between anywhere from 1 MHz to 500 MHz. In regard to claim 14, Caro teaches a mechanical fixing means 101. (Fig. 1 of Caro). In regard to claim 18, Caro teaches the use of LEDs 136 (Fig. 4 of Caro), beam-shaping element 137 (Fig. 4 of Caro), beam-shaping element 117 (Fig. 1 of Caro), and photodetecting elements 304 (Fig. 5 of Caro). In regard to claim 19, Caro teaches that the device is a pulsoximetric sensor. (column 17, lines 3-16 and column 4, lines 38-47 of Caro).

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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- 5. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,348,003 to Caro as applied to claim 14, and further in view of U.S. Patent 4,321,930 to Jobsis et al. (Jobsis). Caro teaches a light source in the form of an optical fiber 116 connected to a clip assembly 101. (Fig. 1 of Caro). Caro does not teach how the optical fiber is connected to the clip assembly. Jobsis teaches that the optical fibers are connected to threaded fittings so that the optical fibers can be connected to attachment assemblies. (column 9, lines 63-66 of Jobsis). Such a teaching would allow the optical fiber to be connected to the clip assembly as required by Caro. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the threaded fittings as disclosed by Jobsis in the invention of Caro since Caro requires a way of attaching the optical fibers to an attachment assembly and Jobsis teaches one such way.
- 6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,348,003 to Caro in view of U.S. Patent 4,321,930 to Jobsis et al. (Jobsis) as applied to claim 15, and further in view of U.S. Patent 4,685,464 to Goldberger et al. (Goldberger). The combination teaches that the clip assembly can use hinges and pivots. (column 6, line 64 to column 7, lines 7 of Caro). Goldberger teaches a hinge and pivot (Fig. 2 of Goldberger) that would fulfill the requirements set forth in the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the hinge and pivot of Goldberger in the

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combination since Caro teaches that hinges and pivots can be used and Goldberger teaches such hinges and pivots.

Response to Arguments

7. Applicant's arguments filed 5/20/2005 have been fully considered but they are not persuasive.

The Applicant has argued that the LEDS shown in Fig. 4 of the Caro patent are not arranged to emit light directly into the area of the tissue. The Applicant contends that the "light in Caro is transferred...from the LEDS via fibers to a modulator 202 and afterwards again via a fiber optic 116 to the measuring array, where first, over a beam splitter and afterwards over focusing means, the light is emitted onto the tissue". The Applicant concludes that there is no direct light emission from the LEDs onto the tissue. First, it is noted that claim 1 does not claim such a structure. Claim 1 includes "two beam shaping elements for directing light emitted by the two LEDs directly from the LEDs and directly to the tissue portion". Thus, claim 1 does not require that there is a direct light emission from the LEDs onto the tissue because there are beam-shaping elements disposed between the LEDs and the tissue. Caro teaches the claimed structure of claim 1 of the present invention because Caro teaches beam-shaping elements in the form of optical fibers 137 (Fig. 4 of Caro), optical modulators (Fig. 4 of Caro), and focusing means 117 (column 7, lines 21-32 of Caro) as required by claim 1 of the present application. Similarly, claim 18 also requires beam-shaping elements disposed between the LEDs and the human tissue, which is disclosed by Caro.

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Next, the Applicant asserts that Caro does not teach the use of optical filters and frequency-sensitive detectors. The Applicant contends that the filter elements and detectors in the detector assembly 141 of Caro have nothing to do with the light transmission within the measuring array as described in the present application and that the reason for filtering and detecting the light within the detector assembly 141 of Caro is a completely different one from the presently claimed invention. This argument is irrelevant. Claims 1 and 5 of the present application are apparatus claims that are not structurally different from the teachings of Caro. The Applicant has even admitted that Caro teaches the use of filter elements and detectors, which is disposed between the light sources and detectors. Thus, Caro meets all the structural limitations of the claimed apparatus.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew Kremer Assistant Examiner Art Unit 3736

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